K120597

MAY 3 2013

Section VII. 510(K) SUMMARY

Date Prepared
May 1, 2013

Name of Firm
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Official Correspondent
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Establishment Number
3005129649

Device Name
Legally Marketed Trade Name: KOMPRESA Facet Screw System
Common Name: Facet Screw System
Device Classification: Unclassified
Reason unclassified: Pre-amendment
Device Product Codes: MRW

Predicate Devices
Trans 1 facet screw (K073515), Depuy Spine's DISCOVERY facet screw system (K012773)

Device Description
The subject Kompresa Facet Screw System consist of non-sterile, single use cannulated screws of various diameters and lengths to be used in conjunction with different diameter nuts and a universal collet. The screws, nuts and collets are all made from titanium alloy

Ti6Al4V. The Instruments and guide wires are made from various grades of stainless steel or aluminum.

Indications for Use

The Kompresa Facet Screw System is indicated for bilateral transfacet fixation and stabilization of the facet joints as an aid to fusion for the treatment of any or all of the following at the T10 to S1 spinal levels:

- Trauma, including spinal fractures and/or dislocation
- Spondylolisthesis
- Spondylolysis
- Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Degeneration of the facets with instability

Materials

The screws, nuts and collets are made from titanium alloy Ti6Al4V. The instruments are made from various grades of stainless steel or aluminum.

Performance Data

Bench testing was performed to support the equivalence of the proposed facet screw system. Axial pullout, and torque to failure tests were performed per ASTM F543-07. Static and dynamic collet/locknut pull off-tests were performed per ASTM 1798. Static three-point bend and dynamic cantilever bend tests were performed per ASTM F1264-03. Static cantilever bend tests were performed per ASTM 2193-02.

Substantial Equivalence Statement

Documentation is provided to demonstrate that the Kompresa Facet Screw System is substantially equivalent to its predicate devices in terms of its material, design, indications for use, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 3, 2013

Custom Spine, Incorporated
% Mr. David L. Brumfield
9 Campus Drive
Parsippany, New Jersey 07054

Re: K120597
Trade/Device Name: KOMPRESA Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: April 19, 2013
Received: April 24, 2013

Dear Mr. Brumfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section VI. INDICATIONS FOR USE STATEMENT

510(k) Number : K120597

The Kompresa Facet Screw System is indicated for bilateral transfacet fixation and stabilization of the facet joints as an aid to fusion for the treatment of any or all of the following at the T10 to S1 (included) spinal levels:

- Trauma, including spinal fractures and/or dislocation
- Spondylolisthesis
- Spondylolysis
- Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Degeneration of the facets with instability

Prescription Use __X____ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

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